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UNCLAS SECTION 01 OF 05 ANKARA 001157

SIPDIS

DEPT FOR EB/TPP/MTA/IPC - SWILSON/JURBAN AND EUR/SE
DEPT PASS USTR FOR LERRION/BPECK
DEPT PASS LIBRARY OF CONGRESS
DEPT PASS USPTO FOR ELAINE WU
USDOC FOR ITA/MAC/DDEFALCO

SENSITIVE

E.O. 12958: N/A
TAGS: ETRD KIPR TU
SUBJECT: Pharmaceuticals Update: Multinationals Threatened by New Pricing Decree

Ref: Ankara 977 and previous

Summary

¶1. (SBU) U.S. companies have complained that a new GOT pricing caps threaten the commercial viability of many of their product lines, and could lead them to delay or suspend the launch of new pharmaceuticals in Turkey. In a letter to USTR, the Foreign Trade Undersecretary maintains that the GOT views data exclusivity as an EU Customs Union obligation rather than a WTO TRIPS requirement, and that this policy will be introduced with an unspecified transition period. The GOT's Council of State rendered a decision limiting the application of "cheapest generic" reimbursement policy in the state pension fund. Embassy requests guidance on the pricing decree, and urges Washington agencies to pursue sustained engagement with the GOT on intellectual property and other WTO issues affecting the pharmaceuticals sector. End Summary.

New Price System A Blow to Research-Based Firms
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¶2. (U) At a February 20 briefing for the Ambassador, U.S. companies expressed serious concern with a February 14 pricing decree. The decree, which is already in force, limits pharmaceuticals prices in Turkey to a maximum of 90 percent of the average of the lowest two prices prevailing in a group of five European countries. While the measure does not appear to address any intellectual property issues, it may contain WTO-inconsistent provisions allowing higher prices for domestically-produced generic drugs, and does not set objective pricing criteria or remedy mechanisms for companies applying under the decree (reproduced in para 9).

¶3. (U) Research-based companies had pressed for changes to the previous pricing system, which applied discriminatory price limits on imported pharmaceuticals, and had even suggested some forms of reference pricing. While the new system eliminates many of those provisions, research-based companies have told us that the new system will render sale of some medicines unprofitable, and could lead to delay or suspension in the launch of new molecules in Turkey. AIFD, the Turkish research-based pharmaceuticals association, has written to the Prime Minister to register its concerns with the decree.

¶4. (SBU) Econoff raised U.S. company concerns with Hayriye Mihcak, the Health Ministry's Director General for Pharmaceuticals, Dilek Emil, the Treasury Undersecretariat's Deputy Director General for Foreign Investment, and Husnu Dilemre, Foreign Trade's Deputy Director General for Multilateral Agreements. All expressed some surprise that research-based companies did not consider the decree an improvement over the previous pricing system. Foreign Trade told us that the Turkish decree was modeled on Portugese and Spanish drug pricing systems.

Data Exclusivity

¶5. (SBU) The GOT has not made an announcement on data exclusivity, though Mihcak told us that the Government planned to make an announcement on this by the end of March. Dilemre also said that a decision on data exclusivity would be announced soon, but emphasized that Turkey viewed this as an EU Customs Union obligation rather than a WTO TRIPS requirement. In a February 11 letter to A/USTR Novelli (reproduced in para 10), Foreign Trade Undersecretary Tuncer Kayalar also made these points, but argued that Turkey would need a transition period for implementation.

Legal Challenge on Reimbursement Policy

¶6. (U) In January 2004, the Council of State (Danistay) issued a ruling restricting application of the "cheapest generic" pharmaceuticals reimbursement policy for the GOT's pension fund. The decision, a preliminary injunction, calls for the GOT to stop implementation, within 30 days, of "cheapest generic" reference pricing. However, industry sources have said that the injunction is likely to be overturned as the case moves through the courts. The Danistay also limited reimbursement of generics to those which the GOT has certified as "bioequivalent" with the brand name molecule. While research-based companies have welcomed the decision, the impact will be limited: industry sources relate that there is now a bioequivalent generic for most original drugs.

Comment/Action Request

¶7. (SBU) Research-based industry is alarmed by the new pricing decree, though its concerns seem to lie more with the pricing formula for brand name drugs than with the parts of the decree (generic pricing, transparency) that could be WTO-inconsistent. Embassy requests Washington agencies' guidance on whether to advocate for change in the pricing formula.

¶8. (SBU) As noted reftel, elevating Turkey in the Special 301 Watch List system, combined with sustained Washington engagement, is our best hope for prodding the GOT to action on data exclusivity and WTO-inconsistent practices. We understand that Commerce A/S Lash and Senator Lugar plan to write to top GOT officials on pharmaceuticals issues. Embassy continues to recommend that Washington agencies also consider dispatching an interagency IPR delegation to Ankara, and sending additional high-level correspondence on these issues, and particularly to rebut the GOT's position that the TRIPS Agreement does not require data exclusivity.

¶9. (U) Begin Text - AIFD Translation of GOT Pricing Decree:

Decision No: 2004/6781
It has been decided to enforce the attached "Decision Regarding the Pricing of Medicinal Product for Human Use" upon the letter dated 21/1/2004 and 003149 of the Ministry of Health, by the Council of Ministers on 6/2/2004.

Decision Regarding the Pricing of Medicinal Products for Human Use

Article 1 - In accordance with "the Law no. 1262 on Pharmaceutical and Medicinal Products" and "the Fundamental Law no. 3359 on Healthcare Services", the Ministry of Health (the Ministry) shall determine the maximum prices by adopting the necessary measures that will be taken to ensure the affordability of medicinal products for human use (products). Companies may request prices below the maximum price. The price approved by the Ministry of Health shall be in effect as of the date of its approval.

Article 2 - The Ministry of Finance shall be authorized to investigate the suitability of these prices to the principles set forth in this Decision.

Article 3- The maximum price of original products, excluding VAT, shall be determined as follows: 2 reference countries with the cheapest prices of the product for which a price is to be determined in Turkey shall be selected out of 5 countries, namely France, Italy, Spain, Portugal and Greece in the year 2004 and to be deemed as suitable among the European Union (EU) countries by the Ministry; the retailer sale price of the product shall be determined by taking as basis maximum 90 percent of the average ex-factory price (sales price to the wholesalers calculated by deducting pharmacy and wholesaler profits from the retailer sale price) of these 2 reference countries and by adding the profit rates of wholesalers and pharmacies to be calculated in accordance with article 10. Should the ex-factory price in the country from where the product is imported be lower than the determined reference price, the profit rates of wholesalers and pharmacies shall be added to the price in the country from where it is imported.

Article 4 - The retailer sales price of generic products, excluding VAT, shall be determined by taking as basis maximum 70 percent of the average of the ex-factory sales price of the original drugs of these products, calculated in accordance with article 3 and adding the profit rates of wholesalers and pharmacies. Yet, the maximum rate may be increased to 80 percent in case it is documented that locally manufactured raw materials have been utilized as the active ingredient of the drug in the production of generic products. In case the ex-factory sales price in the country from where the product is imported, results to be lower than the price determined for the EU countries, the profit rates of the wholesaler and pharmacies shall be added to the price in the pertinent country.

Article 5 - The price of the products not marketed outside Turkey and the products not marketed by the EU countries shall be determined by taking into consideration the principles and the cost factors set forth in articles 3 and 4, provided it does not surpass the price of similar products.

Article 6 - The ex-factory price of the products packed for hospitals shall be determined by taking into consideration the principles and the cost factors set forth in articles 3 and 4, provided it remains at least 10percent below the unit prices of the original products.

Article 7 - A "Price Evaluation Commission" shall be established and convene on a quarterly basis upon the participation of the representatives of the Ministry of Finance, the State Planning Organization and the Turkish Treasury under the coordination of the Ministry of Health, in order to submit proposals to the Ministry of Health for the increase, decrease, or freezing of the price of medicinal products. In case of a change of more than 5percent in the foreign exchange rate within a minimum period of 30 days, the Price Evaluation Commission shall convene on an extraordinary basis, upon the invitation of the Ministry of Health to re-evaluate the prices of products. The secretarial services of the commission in question shall be executed by the Ministry of Health.

A "Reimbursement Commission" shall be established and convene once every 6 months upon the participation of the representatives of the Ministry of Health, the State Planning Organization and the Turkish Treasury, the Social Insurance Institution, Emekli Sandygy and Bad-Kur and upon consulting the views of civil society organizations, under the coordination of the Ministry of Health, in order to submit proposals to the pertinent ministries. The secretarial services of the commission in question shall be executed by the Ministry of Health.

Article 8 - Product manufacturers and importers shall be obligated to document that their products are original or generic. Manufacturers and importers shall be obligated to submit to the Ministry the ex-factory prices in the reference countries together with their requests for obtaining, increasing or decreasing a price. The TL equivalent of the prices determined shall be calculated upon the foreign exchange sales rate of the Central Bank of the Turkish Republic. The price which is deemed suitable shall be approved by the

Ministry within 10 working days. The justification for a price which is not deemed suitable shall be communicated by the Ministry to the concerned company within 10 working days. The pricing transaction shall be executed within 90 working days upon the submission of the valid documentation by the concerned company. This period may be extended by 60 working days in case of accumulation of applications and in periods of heavy workload. In case of failure of the concerned companies to submit their valid documents, the price determined by the Ministry shall be retained valid.

Article 9 - In case of a decrease of 5percent or more in the price of the original product in the reference countries, the company manufacturing or importing the product shall be obligated to apply to the Ministry within 30 days to obtain a new price. A second degree withdrawal transaction shall be implemented on the products for it is determined by the Ministry that no such notification has been made and the registration shall be suspended for a period three times longer than the period in which no notification has been made, including 30 days. The suspension transaction shall be annulled by issuing the new price at the end of this period.

Article 10- The wholesaler and pharmacy profit rates to be implemented when determining the retailer sales price of products in accordance with article 3 and 4, shall be determined in segments as follows, for both imported and local products:

Out of the sales price to wholesalers/Wholesaler (Percent)/Pharmacy (Percent):

Part up to/including 10 million TL: 9, 25
Part between 10 - 50 million TL: 8, 24
Part between 50 - 100 million TL: 7, 23
Part between 100 - 200 million TL: 4, 16
Part above 200 million TL: 2, 10

The Ministry of Health shall be authorized to review these rates by taking into consideration the annual wholesale price index of chemical products of the State Statistics Institute of the former year and the allocation of the total sales of medicinal products in the last 3 years.

Article 11 - Product manufacturers and importers are obligated to adhere to the principles set forth in this Decision. Legal action within the pertinent legislation shall be taken against those in violation of these principles.

Article 12 - The Ministry shall be authorized to issue notifications with regard to the implementation of this Decision.

Article 13 - The Council of Ministers Decision dated 6/2/2002, with no. 2002/4331 has been revoked.

Temporary Article 1- As of the publication date of this Decision, the prices of registered products shall be re-determined in accordance with the principles set forth in this Decision. The concerned companies shall apply to the Ministry upon having compiled the necessary documents in accordance with this Decision, within 45 days as of the publication date of the Decision, in order to establish a basis for the determination of the new prices. The registrations of the products for which no application is submitted within this period shall be suspended until the application date. The sales prices excluding VAT, to be determined in accordance with this article, shall not surpass the price in TL, excluding VAT, on the date of this Decision for local products, and the amount in TL, excluding VAT, corresponding to the foreign exchange sales rate of the Central Bank of the Turkish Republic, on the application date for the product for imported products.

Temporary Article 2- The prices of imported products shall be re-determined ex-officio by the Ministry over the foreign exchange sales rate of the Central Bank of the Turkish Republic on the publication date of this Decision. The new prices shall be retained valid as of the approval date.

Article 14- This Decision shall be enforced as of its publication date.

Article 15- This Decision shall be executed by the Council of Ministers.

End Text - AIFD Translation of GOT Pricing Decree.

¶10. (U) Begin Text - Foreign Trade U/S - USTR Letter

February 11, 2004
Ms. Catherine A. Novelli
Assistant US-Trade Representative for
Europe and the Mediterranean
Dear Ms. Novelli,

I would like to thank you for your letter dated January 14, 2004 which has provided me with the opportunity to clarify the misconception about the compliance of Turkey's IPR legislation with the TRIPS Agreement.

As you will recall, the WTO Members unanimously confirmed the consistency of Turkey's IPR legislation and implementations with the TRIPS Agreement at the TRIPS Council's meeting in Geneva on November 30, 2000.

Besides, as referred in your letter, our authorities are working on a plan to introduce and implement rules and regulations regarding data exclusivity in pharmaceuticals in line with our commitments arising from the Customs Union with the EU.

As you may appreciate, this plan will not only have negative impacts on the consumers and the current public health policies but on the generic industry as well. Therefore, the transition period turns out to be a necessity to offset to a certain extent the economic and social pressures and to avoid any further economic damages that would be recovered at a higher cost otherwise.

On the other hand, I would like to note that my colleagues are doing their best to figure out an option that keeps the transition period as short as possible. At this point, supportive approaches from our trading partners will certainly contribute to the early conclusion of their studies.

Expressing my best wishes and highest regards to you, I remain,

Sincerely Yours,

Tuncer Kayalar
Undersecretary

End Text Foreign Trade/USTR Letter.
Edelman